

Exhibit A

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)
Plaintiff,)
v.)
SAREPTA THERAPEUTICS, INC.,)
Defendant.) C.A. No.
21-1015-GBW
SAREPTA THERAPEUTICS, INC.,)
Defendant/Counter-Plaintiff,)
v.)
NIPPON SHINYAKU CO., LTD. and)
NS PHARMA, INC.)
Plaintiff and Counter-Defendants.)

Wilmington, Delaware
Thursday, August 2023
Motion Transcript

BEFORE: HONORABLE GREGORY B. WILLIAMS
UNITED STATES DISTRICT COURT JUDGE

Michele L. Rolfe, RPR, CRR

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APPEARANCES:

MORGAN, LEWIS & BOCKUS LLP
BY: AMY M. DUDASH, ESQ.
AMANDA S. WILLIAMSON, ESQ.
ALISON PATITUCCI, ESQ.
GUYLAINE HACHE, ESQ.
Attorneys for Plaintiff

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: MEGAN E. DELLINGER, ESQ.

-and-

FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
BY: WILLIAM RAICH, ESQ.
CHARLES LIPSEY, ESQ.
YOONJIN LEE, ESQ.

*Attorneys for Defendant and
Counter-Plaintiff Sarepta
Therapeutics, Inc.*

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P R O C E E D I N G S

(REPORTER'S NOTE: The following motion was held in Courtroom 6B beginning at 11:00 a.m.)

THE COURT: Good morning. You may be seated.

All right. We are here for the hearing on the parties' motions for leave to amend answers in Nippon versus Sarepta. Civil Action No. 21-1015.

The Court has allocated 30 minutes for this hearing. Is that your understanding?

MR. RAICH: I had understood it's 40 minutes.

THE COURT: 40 minutes, that's fine.

MR. RAICH: I'll take every minute, Your Honor.

THE COURT: I have read the parties' submission, we have two motions, one motion by each side.

So let's start with the plaintiff's motion for leave the following amended answer.

MS. DUDASH: Your Honor, Ms. Williamson from Morgan Lewis will be presenting argument on the motions today. I'll be handing up to the Court the two slide decks we have.

THE COURT: I'm sorry, let's allow counsel to put appearances on the record.

MS. DUDASH: Sure. This is Amy Dudash from Morgan Lewis for plaintiff Nippon Shinyaku and NS Pharma.

1 And with me I have also from Morgan Lewis, Amanda
2 Williamson, Allison Patitucci and Guylaine Hache.

3 THE COURT: Good morning.

4 MS. DELLINGER: And good morning, Your Honor.
5 Megan Dellinger from Morris Nichols on behalf of Sarepta and
6 UWA. I'm joined this morning by my co-counsel from William
7 Raich, Charles Lipsey and Yoonjin Lee.

8 THE COURT: Good morning.

9 MS. DELLINGER: And, Your Honor, I just wanted
10 to flag -- I think the parties have worked out how to work
11 around confidential information that's involved, but there's
12 a possibility we may need to make a request to seal the
13 courtroom at some point.

14 THE COURT: Okay. All right.

15 MS. DELLINGER: Thank you.

16 THE COURT: All right. So my understanding with
17 NS motion is it's moving for leave to file an amended answer
18 to add counterclaims of inequitable conduct based knowingly
19 false claims of priority and Walker Process fraud based on
20 Sarepta's assertion of '851, '590 and '827 patents.

21 MS. WILLIAMSON: Yes, that's correct, Your
22 Honor.

23 THE COURT: All right.

24 MS. WILLIAMSON: Good morning, Your Honor.
25 Amanda Williamson on behalf of Nippon Shinyaku and NS

1 claims. They are now saying you can piece together
2 different disclosures, you know paragraph here, a paragraph
3 here to get to that chemical structure. Respectfully,
4 that's really not what could be done.

5 They further argued that the safety information
6 is cumulative because of one sentence in a -- that was
7 recited that said -- in a different document that said that
8 PMOs are generally safe, but this was an extensive study in
9 primates establishing safety.

10 In fact, Nippon Shinyaku's internal documents
11 show that after this publication came out, the Sarepta
12 publication came out, Nippon Shinyaku convened a meeting on
13 their section heads and department heads to specifically
14 discuss this publication and its impact on their exon
15 skipping program. So we think that these are just
16 completely different situations and, in fact, the document
17 is not cumulative.

18 Thank you very much for your patience, Your
19 Honor, I appreciate it.

20 THE COURT: All right. Let's take a 5- to
21 10-minute break and I'll come back with my rulings.

22 (Recess taken.)

23 THE COURT: All right. You may be seated.

24 So first let me start by telling both sides,
25 Mr. Raich and Ms. Williamson, good job.

1 I'll start with Nippon Shinyaku's motion for
2 leave to file amended answer to Sarepta's counterclaims.
3 The Court is going to grant the motion for leave. NS moves
4 for leave to file an amended answer to add counterclaims of
5 inequitable conduct based upon knowingly false claims of
6 priority and Walker Process fraud based on Sarepta's
7 assertion of United States Patent Nos. 9,994,851, 10,227,590
8 and 10,266,827, collectively the Wilton patents.

9 Leave to amend must generally be granted unless
10 equitable considerations render it otherwise unjust. And
11 that's *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (Third
12 Circuit 2006). See also *Foman v. Davis* 371 U.S. 178, 182.

13 The Third Circuit has adopted a liberal approach
14 to the amending of pleadings. If, in the absence of undue
15 delay, bad-faith or dilatory motives on the part of the
16 moving party, the amendment should be freely granted unless
17 it is futile or unfairly prejudicial to the nonmoving party.
18 That's also from those same cases.

19 An amendment is futile if it would fail to state
20 a claim upon which relief could be granted. And that comes
21 from *In re Burlington Coat Factory Securities Litigation*,
22 114 F.3d, 1410, 1434, (Third Circuit 1997). The standard
23 for assessing futility is the same standard for a legal
24 sufficiency as applies under Federal Rules of Civil
25 Procedure 12(b)(6). And that comes from *Great Western*

1 *Mining v. Fox Rothschild, LLP*, 615 F.3d, 159, 175 (Third
2 Circuit 2010).

3 In order to prove undue prejudice, the nonmovant
4 must show that it was unfairly disadvantaged or deprived of
5 the opportunity to present facts or evidence which it had
6 offered had the amendments been timely. And the Court cites
7 to *Bechtel v. Robinson* 886 F.2d 644, 652, (Third Circuit
8 1989). It cites *Heyl & Patterson International, Inc. v.*
9 *F.D. Rich Housing of Virgin Islands, Inc.*, 663 F.2d 419,
10 426, (Third Circuit 1981).

11 Typically the plaintiff in an inequitable
12 conduct dispute has access to all the information that is
13 pertinent to its case; that is the issues of intent and
14 materiality ordinarily turn on evidence in the patentee's
15 possession and often do not require factual discovery. And
16 that comes from *Lipocine* 220 WL 479456 at page 7.

17 For that reason, courts have noted that the loss
18 of an opportunity for discovery on inequitable conduct
19 typically does not result in prejudice to the patentee.

20 Here, because NS's inequitable conduct and
21 Walker Process fraud claims turn on evidence within the
22 patentee's control, i.e., Sarepta, Sarepta will not be
23 prejudiced by NS's proposed amendments.

24 Now turning to futility with respect to
25 inequitable conduct. Rule 9 of the Federal Rules of Civil